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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MICHAEL EPSTEIN and CAROL MILLER, on Behalf of Themselves and All Others Similarly Situated, Plaintiffs, v. NEUTROGENA CORPORATION and JOHNSON & JOHNSON, INC., Defendants.	HON. PETER G. SHERIDAN Case No: 3:12-CV-07576 CLASS ACTION **Motion Returnable: June 17, 2013** **Oral Argument Requested** **MEMORANDUM IN SUPPORT OF NEUTROGENA CORPORATION AND JOHNSON & JOHNSON, INC.'S, MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED CLASS ACTION COMPLAINT PURSUANT TO FED. R. CIV. P. 12(B)(6).**

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

TABLE OF AUTHORITIES

(continued)

Page

TABLE OF AUTHORITIES

(continued)

Page

TABLE OF AUTHORITIES

(continued)

Page

I. INTRODUCTION

Plaintiffs Michael Epstein and Carol Miller's purported amended class action complaint ("Amended Complaint" or "FAC") challenges Johnson & Johnson, Inc., and Neutrogena Corporation's (collectively "Defendants'") "labeling, marketing and sale" of Food and Drug Administration ("FDA")-regulated sunscreen products. Plaintiffs allege that Defendants' labeling and advertising of Neutrogena sun protection products (the "Products") were false and misleading because the Products' labeling and advertising used the terms "sunblock," "waterproof," and "sweatproof" (the "Claims"). (FAC ¶¶ 1-4.)

Plaintiffs premise their Claims on the FDA's Final Rule: Testing and Labeling, 76 Fed. Reg. 35620, 35638, 35643 (June 17, 2011) (codified at 21 C.F.R. § 201.327) (Defendants' Request for Judicial Notice ("RJN"), filed concurrently herewith, Ex. A) which (a) provides that the terms "sunblock," "waterproof," and "sweatproof" are "false and misleading" and may not be used on products manufactured after December 17, 2012; and (b) requires sunscreen products manufactured after December 17, 2012, to indicate that they must be reapplied "at least every two hours." (FAC ¶¶ 45-50.) Plaintiffs seek to recover damages, injunctive relief, and penalties and costs under the New Jersey Consumer Fraud Act (the "NJCFA"), the New Jersey Truth-in Consumer Contract, Warranty and Notice Act (the "TCCWNA"), and for breach of express warranty, on behalf of

themselves and putative New Jersey and multi-state classes of consumers who purchased the Products. (*See* FAC ¶ 6.) Plaintiffs' Amended Complaint should be dismissed for several reasons.

First, Plaintiffs' Claims are expressly and impliedly preempted. Section 379r of the Food, Drug, and Cosmetic Act (the "FDCA") expressly preempts state law requirements that are not identical to federal regulations governing over-the-counter drugs such as sunscreens. 21 U.S.C. § 379r. The FDA itself has opined that its Final Rule preempts "States from issuing requirements related to the labeling and testing of OTC sunscreen drug products that are different from or in addition to, or not otherwise identical with a requirement in the final rule." 72 Fed. Reg. 49070, 49109 (Aug. 27, 2007) (Proposed Rule: UV Testing and Labeling) (RJN Ex. B); *see also* 76 Fed. Reg. at 35624, 35658. The Final Rule did not preclude use of the terms "sunblock," "waterproof," and "sweatproof" prior to December 17, 2012. Prior to issuing the Final Rule, the FDA considered arguments from the public "that 'sunblock,' 'waterproof,' and 'sweatproof' claims are false and misleading." 76 Fed. Reg. 35620, 35643. Yet the FDA expressly concluded that sunscreen manufacturers could continue to manufacture sunscreen products containing the terms for 18 months after the Final Rule. *Id.* at 35624; 77

Fed. Reg. 27591[1] (extending compliance date). Plaintiffs' claims, which ask this Court to second-guess the FDA, are preempted.

Plaintiffs' Claims premised on violation of the FDCA or other federal regulations—and all or virtually all of Plaintiffs' Claims appear to fall into this category—also are preempted.

Second, Plaintiffs' Claims should be dismissed under the primary jurisdiction doctrine. The regulatory history for sunscreen products is extensive and dates back to 1978. The regulations are informed by evolving and complex scientific and technical studies. And, while the FDA has expressly said that states should not impose requirements that differ from or are not identical with its Final Rule, Plaintiffs' Claims only survive if this Court does precisely that. Absent deference to the FDA, Defendants run the risk of facing different obligations in different states, notwithstanding the comprehensive federal regulatory scheme. The Court should defer primary jurisdiction to the FDA.

Third, Plaintiffs lack Article III standing to pursue certain of their Claims. Although Plaintiffs appear to seek relief related to all of the Products (*see, e.g.*, FAC ¶ 1), Plaintiffs allege only that they purchased "several" of these Products. As to these alleged "several" Products, Plaintiffs identify only three that they in

[1] Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates ("Compliance Dates"), 77 Fed. Reg. 27591 (May 11, 2012) (RJN Ex. C).

fact purchased. (FAC ¶¶ 10-11.) Plaintiffs have no standing to maintain claims based on non-purchased Products.

Plaintiffs also lack standing to seek injunctive relief. Because Plaintiffs have not alleged, and cannot allege, a risk of future harm, and because Plaintiffs are now aware of the purported false labeling, they cannot establish Article III standing to support their requests for injunctive relief.

Fourth, Plaintiffs' consumer fraud Claims fail because they are not pleaded with the particularity required by Federal Rule of Civil Procedures 9(b). *See* Fed. R. Civ. P. 9(b). Other than a generic statement that Plaintiffs allegedly "viewed" the terms "sunblock," "waterproof," and "sweatproof" on three of the Products they "purchased" in "New Jersey," Plaintiffs allege no factual details of the circumstances of their alleged purchases. Plaintiffs do not allege *where* in New Jersey they purchased the Products, *when* they allegedly purchased the Products (month, season, or year), *how* much either Plaintiff paid for any Product, or *which other* sun protection products they reviewed and considered before purchasing the Products. They do not allege their intended or actual use of the Products, including whether they applied the Products as directed. Nor do they allege facts specific to how the Products failed to perform after Plaintiffs applied the Products and were exposed to the sun, water, or sweat. With necessary detail lacking, it is impossible to assess whether Plaintiffs were in fact injured by their alleged purchase of any (or

all) of the Products.[2]

Plaintiffs' NJCFA Claims also fail to sufficiently plead any "ascertainable loss"—a condition precedent to alleging a private NJCFA claim.

Fifth, Plaintiffs' express warranty Claims are barred in part to the extent they purport to extend the class period beyond New Jersey's four-year statute of limitations for breach of warranty. Additionally, to the extent Plaintiffs assert any express warranty claims based on any marketing, promotion or advertising for the Products, Plaintiffs fail to plead such claims sufficiently.

II. BACKGROUND

A. Plaintiffs' Amended Complaint.

The crux of Plaintiffs' Claims is that the Products allegedly "d[id] not block all[,] or anywhere close to all[,] of the sun's rays" and that the protection provided by the Products "were not impenetrable to and unaffected by water or sweat and, thus, were not truly 'waterproof' or 'sweatproof.'" (FAC ¶¶ 3-4.) Therefore, according to the Amended Complaint, the Products did not provide "sunblock" protection and were "not truly 'waterproof' or 'sweatproof.'" (*Id.*) Plaintiffs allege that Defendants "knew or should have known" that these Products did not provide "sunblock," "waterproof," or "sweatproof" protection (*id.*), and through

[2] To the extent Plaintiffs' TCCWNA claim is premised on fraud (as opposed to violations of the Final Rule and FDCA), it too must be dismissed for failure to plead fraud with requisite particularity.

their "deceptive and misleading product labels . . . led consumers to believe that [the Products] provide [such protection]." (*Id.* ¶ 2.) Citing the Final Rule, Plaintiffs allege that the FDA has identified these terms as "false and misleading" and "expressly prohibit[ed]" their use. (FAC ¶¶ 45-50.) They allege that Defendants "acted unconscionably and with a willful and conscious disregard for the health and safety of others." (FAC ¶ 50.)

Plaintiffs purport to allege violations of the NJCFA and the TCCWNA, and breaches of express warranty. (*See* FAC ¶ 6.) They seek to certify: (1) a statewide class of "[a]ll natural persons who purchased a Neutrogena Sun Protection Product in the state of New Jersey at any time from six years prior to the date when the initial complaint was filed through the present;" and (2) a multi-state class of "[a]ll natural persons who purchased a Neutrogena Sun Protection Product in any state with laws similar to those of New Jersey at any time from six years prior to the date when the initial complaint was filed through the present." (FAC ¶¶ 21, 29.) Plaintiffs seek, *inter alia*, a permanent injunction, restitution, actual damages, treble damages, a refund of all moneys acquired, statutory penalties pursuant to N.J. Stat. § 56:12-17, attorneys' fees, filing fees, and costs of suit. (FAC at Prayer.)

B. Sunscreen Regulatory History.

The regulatory history of sunscreen is long and complex. The FDA has regulated sunscreen products, including SPF values, since 1978. *See, e.g.*, Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Rule, 43 Fed. Reg. 38206 (Aug. 25, 1978) (RJN Ex. D). The FDA published a Final Monograph intending to regulate the testing and labeling of sunscreen products in 1999,[3] but indefinitely stayed its effective date pending further regulatory review.[4] In 2007, the FDA published a Proposed Amendment to the Final Monograph that would revise UVA and UVB testing and labeling requirements, as well as other aspects of the Final Monograph.[5] In the Proposed Amendment, the FDA specifically stated that "Manufacturers can continue to use existing labeling until the compliance dates of a final rule based on this proposal." 72 Fed. Reg. at 49077; *see also* Final Monograph, 76 Fed. Reg. at 27666, 27684 (specifically allowing manufacturers until twelve months after the effective date of the Final Monograph to relabel their products and stating that existing products did not have to be pulled from the market or relabeled).

[3] *See* 21 C.F.R. § 330.10 (monograph system for OTC drugs); Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph, 64 Fed. Reg. 27666 (May 21, 1999) (codified at 21 C.F.R. pt. 352) (RJN Ex. E).
[4] Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay; Final Rule, 66 Fed. Reg. 67485 (Dec. 31, 2001) (RJN Ex. F).
[5] 72 Fed. Reg. 49070.

After working through thousands of comments to the Proposed Amendment, in 2011 the FDA promulgated the Final Rule separate from the (still-stayed) Final Monograph so that the agency could work "on remaining issues that need to be addressed in order to publish a final monograph."[6] The FDA explained that the Final Rule "embod[ies] the agency's current determination on appropriate regulation of [testing and labeling] of sunscreens . . . and supersede[s] the prior approach embodied in the never-effective provisions of 21 CFR part 352 subparts C and D."[7] The Final Rule provided that "sunscreen products which are already distributed by the effective date of the final rule would not be expected to be relabeled or retested in conformity with the final rule."[8] Manufacturers, including Defendants, had until December 17, 2012, to comply with the Final Rule.[9]

III. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), Plaintiffs' Amended Complaint must be dismissed unless Plaintiffs allege facts that, if true, would "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere

[6] Final Rule, 76 Fed. Reg. 35620, 35621.
[7] *Id.* The FDA also stated that "[the Final Rule] codifies certain specific claims that render a covered product misbranded or are not allowed on any OTC sunscreen drug product marketed in the United States without an approved application." *Id.*
[8] 76 Fed. Reg. 35620, 35624.
[9] 77 Fed. Reg. 27591.

conclusory statements, do not suffice." *Id.*; *see also Bistrian v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012) ("allegations that are no more than conclusions and thus not entitled to the assumption of truth"). Unless Plaintiffs plead concrete facts that, if true, would "nudge[] the[] claims across the line from conceivable to plausible," the Court must grant this Motion. *Twombly*, 550 U.S. at 570.

Where, as here, a plaintiff's "claims sound in fraud," the heightened pleading standards of Rule 9(b) also apply. *See Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 91 (D.N.J. 2011) ("To the extent that Plaintiffs' claims sound in fraud or misrepresentation they 'must state with particularity the circumstances constituting fraud.'") (*citing* Fed. R. Civ. P. 9(b)).

When ruling on a motion to dismiss, a court generally "may not consider matters outside the pleadings," but "may consider documents that are 'integral to or explicitly relied upon in the complaint.'" *Arcand v. Brother Int'l Corp.*, 673 F. Supp. 2d 282, 291 (D.N.J. 2009) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999)). A court may also properly consider "an undisputedly authentic document that a defendant attaches as an exhibit," as well as "public documents." *Id.* at 291-92.

IV. ARGUMENT

A. Plaintiffs' Claims Are Preempted By Federal Law.

The Supremacy Clause invalidates any state law that conflicts with federal law. U.S. Const. art. VI, cl. 2; *Cipollone v. Liggett Grp.*, 505 U.S. 504, 516 (1992) ("state law that conflicts with federal law is 'without effect'") (citation omitted); *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 447 (D.N.J. 2003) (same). "Congress can define explicitly the extent to which its enactments pre-empt state law," often referred to as "express" preemption, or it can impliedly preempt state law if such an intent is evidenced by its enactments. *Fasano v. FRB*, 457 F.3d 274, 280 (3d Cir. 2006); *English v. Gen. Elec. Co.*, 496 U.S. 72, 78-79 (1990). Congressional intent is thus the "ultimate touchstone in every preemption case." *Holk v. Snapple Bev. Corp.*, 575 F.3d 329, 334 (3d Cir. 2009) (citations omitted); *see also Cipollone*, 505 U.S. at 516. Congress has unambiguously indicated its intent to expressly and impliedly preempt state claims, like Plaintiffs', that impose sunscreen labeling requirements differing from or in addition to those required by federal regulations.

1. Plaintiffs' Claims Are Expressly Preempted Under Section 379r of the FDCA.

The FDA's Final Rule codifies the agency's regulation of over-the-counter ("OTC") sunscreen products and preempt any differing or additional state law requirements. Congress included an express preemption provision in the FDCA:

> *National uniformity* for nonprescription drugs . . . [N]o State or political subdivision of a State may establish or continue in effect any *requirement*—(1) that relates to the regulation of a [OTC] drug . . .; and (2) *that is different from or in addition to, or that is otherwise not identical with, a requirement under the [FDCA]*.

21 U.S.C. § 379r(a) (emphases added); *see also Crozier v. Johnson & Johnson Consumer Cos.*, No. 12-0008, 12-0010, 2012 U.S. Dist. LEXIS 140320, at *23-24 (D.N.J. Sept. 28, 2012) (holding that FDA's regulations of labeling of OTC antiseptic product preempted state law claims challenging labeling); *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1286 (C.D. Cal. 2008) ("[I]f the defendant is in full compliance with FDA regulations, any non-parallel state law liability, including a jury verdict for damages, imposes a 'requirement' that is expressly preempted."). The FDA has expressed its view that its Final Rule preempts "States from issuing requirements related to the labeling and testing of OTC sunscreen drug products that are different from or in addition to, or not otherwise identical with a requirement in the final rule." 72 Fed. Reg. 49070, 49109; *see also* 76 Fed. Reg. 35620, 35624, 35658.

The Final Rule did not preclude use of the terms "sunblock," "waterproof," and "sweatproof" prior to December 17, 2012. The FDA concluded that sunscreen manufacturers could continue to manufacture products containing these terms for 18 months after issuance of the Final Rule. 76 Fed. Reg. 35620, 35624, 35643; 77

Fed. Reg. 27591 (May 11, 2012) (extending compliance date).[10] The FDA could have, but did not, require immediate labeling revisions.[11] It could have, but did not, require manufacturers to pull products containing the terms from retail shelves. Plaintiffs do not allege that any Product manufactured by Defendants after December 17, 2012, contains these terms. They seek, instead, to hold Defendants liable for failing to modify their labeling *before* the FDA required the modifications.

Plaintiffs therefore seek to impose different labeling requirements on a different timetable than that established by the FDA, which is precisely what the express preemption provision precludes. *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 795 (2002) ("[W]hen a state law claim, however couched, would effectively require a manufacturer to include additional or different information on a federally approved label, it is preempted." (citations omitted)). In *Kanter*, the Court of Appeal addressed similar consumer protection challenges to OTC-drug's labels, and explained that such claims are "bottomed on the assertion that this [FDA-] approved label is no longer accurate or adequate and that the label

[10] The FDA concluded that manufacturers did not have to remove the terms or relabel "products introduced or delivered for introduction into interstate commerce prior to the compliance dates specified for th[e] final rule," *i.e.*—December 17, 2012. *Id.*

[11] The FDA determined that the large costs associated with relabeling products warranted a longer compliance period. *See*, *e.g.*, 76 Fed. Reg. at 35623-24; 72 Fed. Reg. at 49109.

should be changed or the product banned. Each cause of action would result in the establishment of a state requirement regarding labeling that would be 'different from' and 'otherwise not identical with' the federally required label . . . and each is therefore preempted" by section 379r. *Id.* at 796.[12] That is what Plaintiffs are attempting here—alleging that compliance with *current* federal regulations governing sunscreen labeling, including compliance dates, is inadequate, and that state law requires some additional or different disclosures about sun protection.[13]Plaintiffs' claims are therefore expressly preempted.

2. **Plaintiffs' Claims Are Impliedly Preempted.**

a. Conflict Preemption Precludes Plaintiffs' Claims.

[12] Similarly, in *Carter*, the court dismissed state law claims for damages and injunctive relief based on allegedly misleading statements about the effectiveness of OTC cough and cold medicines. 582 F. Supp. 2d at 1290. Because the challenged statements were based entirely upon FDA-approved labeling and advertising, the court held that plaintiffs' false and misleading advertising, and unfair and deceptive business practices claims were preempted. *Id.* at 1277, 1284. *See also Crozier*, 2012 U.S. Dist. LEXIS 140320, at *25-26 (plaintiff's state law consumer claims challenging the use of a trademark on an OTC antiseptic product as misleading were preempted because "FDA regulations cover the entire label, including indications of a product's brand name, and thus preempt challenges to a label[.]").

[13] It is unclear from the Amended Complaint if Plaintiffs allege any omission-based theories of liability. Even if they did, such claims would similarly fail. Seeking additional disclosures—*e.g.*, that the sunscreen does not block all of the sun's rays—goes beyond what the FDA requires. *See, e.g.*, *Carter*, 582 F. Supp. 2d at 1282, 1290 (preempting claims challenging defendant's failure to put additional warnings on products because such warnings were in addition to requirements imposed by FDA regulations).

Even absent express preemption, Plaintiffs' Claims are impliedly preempted because they conflict with the Final Rule. Conflict preemption arises when it is impossible to comply with both state and federal law, or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881-82 (2000); *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 249-50 (3d Cir. 2008). The FDA, in accordance with its congressional mandate to regulate sunscreen products, evaluated the costs and burdens of relabeling products in light of the relative risks to the public, and determined to not require relabeling of products manufactured prior to the effective date of the Final Rule. 76 Fed. Reg. at 35624, 35655-59. Plaintiffs seek to impose liability on Defendants for doing precisely what the FDA determined they could do: continue to label their Products with the terms "sunblock," "waterproof" and "sweatproof" until the Final Rule took effect.

Imposing an earlier compliance date on Defendants would stand as a direct obstacle to the FDA's objectives in regulating sunscreen products. *See Reid v. Johnson & Johnson*, No. 11-CV-1310, 2012 U.S. Dist. LEXIS 133408, at *21-22 (S.D. Cal. Sept. 17, 2012) (plaintiff's claims impliedly preempted because, *inter alia*, they "seek[] to impose a different, outdated interim rule requirement for Defendants from that set forth in the 2003 FDA Letter and 21 C.F.R. 101.83"); *Geier*, 529 U.S. at 881-82 (interim regulation, motivated by Secretary of

Transportation's desire to foster gradual development of restraint devices, impliedly preempted state law tort action for failing to include a vehicle side airbag earlier than required by federal regulation).

b. Plaintiffs' Claims Based on Alleged Violation of the FDCA are Impliedly Preempted.

To the extent Plaintiffs' Claims are premised on an alleged violation of the FDCA, they are impliedly preempted. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) ("[W]ere plaintiffs to maintain their [claims] here, they would not be relying on traditional state tort law which had predated the federal enactments in question[]. On the contrary, the existence of these federal enactments is a critical element of their case."); *see also Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) ("plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)").[14]

Plaintiffs may bring a state law claim that parallels the FDCA, but they must allege claims that "sound[] in traditional principles of state law and would give rise

[14] Plaintiffs acknowledge that the Final Rule governs Defendants' Product labeling. (*See* FAC ¶ 45.) Plaintiffs do not and cannot allege that Defendants have failed to meet the Final Rule's compliance deadlines. If and to the extent Plaintiffs argue that Defendants violated some other regulations, *see, e.g.*, FAC ¶ 81 (citing 58 Fed. Reg. 28194 (May 12, 1993) and 64 Fed. Reg. 27666 (May 21, 1999)), those regulations were either proposals or rules that never took effect. 76 Fed. Reg. at 35621 (stating the Final Rule "supersede[s] the prior approach embodied in the never-effective provisions of 21 CFR part 352 subparts C and D.") (emphasis added). There is no violation of any federal regulation.

to recovery even had the FDCA never been enacted." *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 375 (E.D.N.Y. 2010) (*citing Riley*,625 F. Supp. 2d at 777). Plaintiffs do not allege their TCCWNA claim independent of the alleged violation of the FDCA and its implementing regulations. Plaintiffs cite various "clearly established legal right[s]" that Defendants allegedly violated. (FAC ¶ 81.) All but two of those alleged "rights" stem from the FDCA and its implementing regulations. *See* FAC ¶ 81 (citing violation of N.J.A.C. § 8:21-1.4 (incorporates FDA regulations by reference), N.J. Stat. § 24:5-1, 24:5-18; 24:5-18.1 (mini FDCA); 21 U.S.C. §§ 352, 362 (FDCA).[15] Plaintiffs' TCCWNA claims based on these alleged violations are thus impliedly preempted. *See Riley*, 625 F. Supp. 2d at 776-777 ("[A] private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist.").

B. <u>The Primary Jurisdiction Doctrine Favors Deference to the FDA.</u>

Plaintiffs' Claims also should be dismissed on primary jurisdiction grounds. Under the primary jurisdiction doctrine, "when an activity is arguably subject to an administrative agency's expertise, such as the FDA, federal courts must defer to

[15] The remaining two grounds alleged by Plaintiffs as a basis for their TCCWNA claims (violations of the NJCFA and N.J. §56:8-1) are defectively pleaded and cannot serve as a "clearly established legal right" allegedly violated by Defendants.

the exclusive competence of that agency." *In re Human Tissue Prods. Liab. Litig.*, 488 F. Supp. 2d 430, 432 (D.N.J. 2007) (citing *United States v. W.P.R. Co.*, 352 U.S. 59, 63 (1956)). Primary jurisdiction is appropriate in "cases where protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Clark v. Actavis Grp. hf*, 567 F. Supp. 2d 711, 715 (D.N.J. 2008). The doctrine promotes "[u]niformity and consistency in the regulation of a business entrusted to a particular agency, the utilization of an agency's specialized knowledge and insight gained through experience, and the exercise of administrative discretion in affecting regulatory policy entrusted to an agency." *IPCO Safety Corp. v. Worldcom, Inc.*, 944 F.Supp. 352, 356 (D.N.J. 1996).

"[T]he possibility that a conflict may arise if a court were to decide a matter inextricably intertwined with an intensive regulatory scheme requires judicial abstention in such cases." *Torres–Hernandez v. CVT Prepaid Solutions, Inc.*, No. 08-CV-1057 (FLW), 2008 U.S.Dist. LEXIS 105413, at *8 (D.N.J. Dec. 9, 2008); *see also Cheyney State College Faculty v. Hufstedler*, 703 F.2d 732, 736 (3d Cir. 1983); *MCI Commc'n Corp. v. Am. Tel. & Tel., Inc.*, 496 F.2d 214, 220 (3d Cir. 1974) (finding that doctrine was created to "avoid conflict between the courts and an administrative agency arising from either the court's lack of expertise with the subject matter of the agency's regulation or from contradictory rulings by the

agency and the court").

Whether the doctrine of primary jurisdiction applies is determined on a case-by-case basis. *Global Naps, Inc. v. Bell Atlantic—New Jersey, Inc.*, 287 F.Supp.2d 532, 549 (D.N.J. 2003). Although there is "no fixed formula for determining whether the doctrine of primary jurisdiction applies," courts consider the following factors: (1) whether the question at issue involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made. *Id.*; *IPCO*, 944 F. Supp. at 356; *see also Clark*, 567 F. Supp. 2d at 715-19; *Holder v. Gold Fields Mining Corp.*, 506 F. Supp. 2d 792, 803 (N.D. Okla. 2007) (invoking primary jurisdiction appropriate when requesting injunctive relief); *accord, e.g.*, *Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 781 (9th Cir. 2002) .

As discussed *supra*, the FDA already expressed its rationale and decision to not require compliance with the labeling requirements in the Final Rule until after December 17, 2012. *See* 76 Fed. Reg. 35620, 35624; Draft Guidance for Industry, 76 Fed. Reg. 35665 (RJN Ex. G); Guidance for Industry: Enforcement Policy-OTC Sunscreen Drug Products Marketed Without an Approved Application (June 2011) ("Guidance for Industry") (June 17, 2011) (RJN Ex. H). It reached this

determination after weighing all of the public costs and benefits, and its reasoned determinations should not be undermined through private litigation. This Court has and should exercise discretion to abstain from addressing these questions and to defer regulatory jurisdiction to the FDA.

C. Plaintiffs Lack Article III Standing.

1. Plaintiffs Lack Standing to Bring Claims Related to Products They Neither Purchased Nor Used.

Plaintiffs must have standing to bring claims in federal court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559-60 (1992). Standing for each of Plaintiffs' claims requires them to show that they suffered injury-in-fact as a result of an allegedly misleading statement. *Id.* at 561; *see Oregon v. Legal Servs. Corp.*, 552 F.3d 965, 969 (9th Cir. 2009) (standing is required for each claim and each form of relief) *abrogated on other grounds* as stated in *Bond v. United States*, --- U.S. ---, 131 S. Ct. 2355, 2361 (2011). Thus, under federal law, Plaintiffs must identify a particularized injury-in-fact that affected each of them personally. *Lujan*, 504 U.S. at 560-61. "Particularized" in this context means the "injury must affect the plaintiff in a personal and individual way." *Id.* at 560 n.1; *see also Lieberson v. Johnson & Johnson Consumer Cos.*, 865 F. Supp. 2d 529, 537 (D.N.J. 2011) ("Plaintiff cannot establish standing to pursue a claim that products she neither purchased nor used did not work as advertised.").

Plaintiffs do not allege that they purchased most of the Products that are the

subject of their Amended Complaint.[16] Plaintiffs, in fact, identify only three Products by name that they allegedly purchased: Neutrogena Ultra Sheer Dry-Touch Sunblock SPF 30 Lotion, Neutrogena Wet Skin Sunblock Spray SPF 30, and Neutrogena Wet Skin Sunblock Spray SPF 85+. (FAC ¶¶ 10-11.)[17] Plaintiffs do not, nor could they, allege that they parted with any money or were damaged in any way by Products they neither purchased nor used. Nor do they claim that they even considered purchasing any of these other Products or read any of the product packaging or ingredient lists for any of these other Products. Plaintiffs cannot lump together vastly different sunscreen products[18] manufactured by Neutrogena

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[16] For this reason, Defendants move, in the alternative, pursuant to Federal Rule of Civil Procedure 12(f) to strike from the pleadings any and all reference to products Plaintiffs neither purchased nor used, including but not limited to: (1) Neutrogena Fresh Cooling Body Mist Sunblock Spray SPF 45; (2) Neutrogena Healthy Defense Oil-Free Sunblock Lotion SPF 45; (3) Neutrogena Wet Skin Kids Sunblock Lotion SPF 45; (4) Neutrogena Ultra Sheer Dry-Touch Sunblock SPF 55; and Neutrogena Clear Face Break-out Free Liquid-Lotion Sunblock SPF 55. (*See* FAC ¶¶ 57-61.)

[17] It is unclear from the face of the Amended Complaint whether Plaintiffs purchased any of the other products mentioned in the Amended Complaint, including: (1) Neutrogena Fresh Cooling Body Mist Sunblock Spray SPF 45; (2) Neutrogena Healthy Defense Oil-Free Sunblock Lotion SPF 45; (3) Neutrogena Wet Skin Kids Sunblock Lotion SPF 45; (4) Neutrogena Ultra Sheer Dry-Touch Sunblock SPF 55; and Neutrogena Clear Face Break-out Free Liquid-Lotion Sunblock SPF 55. (*See* FAC ¶¶ 57-61.)

[18] One look at the Products' names referenced in the Amended Complaint shows that the Products are materially dissimilar. (*See* FAC ¶¶ 57-61.) Apart from their different SPF values, the Products differ substantially in their delivery mechanisms and targeted uses: Neutrogena Fresh Cooling Body Mist Sunblock Spray SPF 45 is a cooling mist; Neutrogena Healthy Defense Oil-Free Sunblock Lotion SPF 45 is a lotion targeting oil-free sunscreen users; Neutrogena Wet Skin Kids Sunblock

based on the purchase of only three of those Products. Plaintiffs cannot have suffered any injury—economic or otherwise—because of products they never purchased nor used. *See Lieberson*, 865 F. Supp. 2d at 537.[19]

Plaintiffs' claims over the Products they neither purchased nor used would unquestionably fail if they were brought on an individual basis, and the result is no different here simply because they filed their Amended Complaint as a putative class action. The rules of procedure cannot modify or enlarge any underlying substantive rights. 28 U.S.C. § 2072(b). In *Amchem Prods., Inc. v. Windsor*, the Supreme Court applied this principle to class actions specifically and held: "Rule 23's requirements must be interpreted in keeping with Article III constraints, and with the Rules Enabling Act, which instructs that rules of procedure 'shall not abridge, enlarge or modify any substantive right.'" 521 U.S. 591, 613 (1997) (quoting, in part U.S.C. § 2072(b)); *see also Lieberson*, 865 F. Supp. 2d at 537 ("[T]he standing inquiry does not change in the context of a putative class

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Lotion SPF 45 is a spray that adults can use on children when they are still wet; Neutrogena Ultra Sheer Dry-Touch Sunblock SPF 55 is a lotion with a special lightweight formula; and Neutrogena Clear Face Break-out Free Liquid-Lotion Sunblock SPF 55 is a liquid for skin prone to acne break outs. (*Id.*)

[19] *See also Green v. Green Mt. Coffee Roasters, Inc.*, 279 F.R.D. 275, 280 (D.N.J. 2011) (class representative did not have standing to pursue claims regarding all Keurig Brewing Systems (the products)—only the particular model that he actually purchased); *Hemy v. Perdue Farms, Inc.*, No. 11-888, 2011 U.S. Dist. LEXIS 137923, at *28-31 (D.N.J. Nov. 30, 2011) (dismissing claims against a particular brand of chickens because plaintiffs did not allege they bought such products, thus failed to "sufficiently allege an injury-in-fact with respect to those products.").

action[.]"); *Hemy*, 2011 U.S. Dist. LEXIS 137923, at *32 (plaintiffs "cannot rely on 'injuries suffered by other, unidentified members of the class.'") (citations omitted). A federal court presiding over a similar putative class action involving sunscreen products dismissed similar claims for products the plaintiff neither purchased nor used. *See* Minute Order at 3 (RJN Ex. I.) Here, too, Plaintiffs lack standing to bring claims based on Products they did not purchase or use.

2. Plaintiffs Have No Standing to Pursue Claims For Injunctive Relief.

Plaintiffs' claims for injunctive relief fail because Plaintiffs do not and cannot allege that they are threatened by any repetition of the injury they claim to have suffered. To have standing in federal court to assert a claim for injunctive relief, Plaintiffs must demonstrate that they are "realistically threatened by a repetition of [the violation]." *Lyons*, 461 U.S. at 109. Where Plaintiffs cannot demonstrate the threat of repetition, their claims for injunctive relief will fail. *See, e.g.*, *McNair v. Synapse Grp., Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) ("When, as in this case, prospective relief is sought, the plaintiff must show that he is 'likely to suffer future injury' from the defendant's conduct (citations omitted). In the class action context, that requirement must be satisfied by at least one named plaintiff.").

For example, in *Robinson v. Hornell Brewing Co.*, No. 11-2183, 2012 U.S. Dist. LEXIS 51460, at *7-14 (D.N.J. Apr. 11, 2012), the court found that the plaintiff lacked Article III standing to represent a class seeking injunctive relief

because he failed to demonstrate that he was likely to suffer future injury from defendant's allegedly misleading use of "All Natural" labeling. The court rejected plaintiff's claims that it was still possible for him to be misled in the future, reasoning that this was too hypothetical or conjectural of a future injury to create standing to pursue injunctive relief. *Id.*

Similarly, in *Wang v. OCZ Tech. Grp., Inc.*, the plaintiff lacked standing to pursue claims for injunctive relief under the consumer protection laws because he had already purchased the defendant's solid state drive and was "in no danger of doing so again." 276 F.R.D. 618, 626-27 (N.D. Cal. 2011); *see also Cattie v. Wal-Mart Stores, Inc.*, 504 F. Supp. 2d 939, 951–52 (S.D. Cal. 2007) (expressing "concern[] that Plaintiff may lack standing to seek injunctive or declaratory relief under [state's consumer protection law] or any other statute" where plaintiff had already purchased the product and there was no suggestion that she intended to buy the product again in the future).

Plaintiffs have not alleged that they intend to purchase any of the Products in the future. Nor could they credibly allege that, should they decide to purchase the Products again, they would somehow be misled by the labeling.

Further, Plaintiffs do not and cannot allege that any Product manufactured after the Final Rule compliance date of December 17, 2012, fails to comply with the Final Rule. Defendants' compliance with current regulations and continuing

regulatory oversight by the FDA obviates any need for declaratory or injunctive relief.

D. Plaintiffs' Remaining Claims Fail to State A Claim Upon Which Relief Can Be Granted.

1. Plaintiffs Fail to State A Claim Under the New Jersey Consumer Fraud Act.

Plaintiffs' allegations do not support a claim under the NJCFA. To state a claim under the NJCFA, a private plaintiff must allege (1) unlawful conduct by the defendant; (2) an ascertainable loss on the part of the plaintiff; and (3) a causal relationship between the defendant's unlawful conduct and the plaintiff's ascertainable loss. *See, e.g., Capogrosso v. State Farm Ins. Co.*, No. 08-CV-2229, 2009 WL 3447068, at *2 (D.N.J. Oct. 21, 2009). Plaintiffs allege that Defendants' labeling[20] of the Products "constitutes an affirmative misrepresentation(s) of fact and a deception, fraud, false pretense, and/or false promise." (FAC ¶ 66.) Because Plaintiffs' NJCFA claim sounds in fraud, their allegations in support must be pleaded with particularity under the heightened pleading standard of Rule 9(b). Fed. R. Civ. P. 9(b); *see Capogrosso*, 2009 WL 3447068, at *7 ("Importantly,

[20] Plaintiff fails to make any specific allegations concerning any marketing, promotion, or advertising beyond the Products' labeling. As such, Plaintiffs have failed to allege any NJCFA claim based on such conduct. *See, e.g., Lieberson*, 865 F. Supp. 2d at 539 (dismissing any NJCFA claims "with regard to any misrepresentations or omissions made by Defendants and disseminated by way of television commercials, print advertisements, website or any medium other than the Product labels themselves" for failure to plead with particularity).

[NJCFA] claims 'sounding in fraud' are subject to the particularity requirements of Federal Rule of Civil Procedure 9(b)." (citations omitted)); *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 98 (D.N.J. 2011) ("Rule 9(b) . . . applies to claims under the Consumer Fraud Act."); *FDIC v. Bathgate*, 27 F.3d 850, 876-77 (3d Cir. 1994) (affirming district court's application of Rule 9(b) to Consumer Fraud Act claim). To satisfy this standard, a plaintiff "must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Glushakow v. Boyarsky*, No. 11-2917, 2011 U.S. Dist. LEXIS 90586, at *7-9 (D.N.J. Aug. 15, 2011) (dismissing plaintiff's NJCFA claim for "failure to comply with the pleading requirements of Rule 9(b)").

Plaintiffs fail to meet this standard, providing no real details of their purchases of any of the Products at issue. Other than a generic statement that Plaintiffs "viewed" the terms "sunblock," "waterproof," and "sweatproof" on the "labeling" of the three Products that they "purchased" in "New Jersey," (*see* FAC ¶¶ 10-12), Plaintiffs allege no factual details regarding the circumstances of their alleged purchases of any Products.

Critically absent are any allegations of *where* in New Jersey Plaintiffs purchased the Products, *when* they allegedly purchased the Products (month, season, or year), *how* much either Plaintiff paid for any one Product, or *which other* sun protection products they reviewed and considered before purchasing

Defendants' Products. Nor do the Plaintiffs allege their intended or actual use of the Products or expectations regarding the Products' performance.

Instead, Plaintiffs allege in conclusory fashion that the Products' purported "benefits were not received by Plaintiffs,"[21] and that "the difference in value of benefits promised and those actually received can be reasonably and objectively quantified as approximately 15% of the purchase price of the respective product." (*Id.* ¶ 13.) Such conclusory allegations are insufficient to plead "ascertainable loss." *Lieberson*, 865 F. Supp. 2d at 537 (dismissing NJCFA claims based on unsupported conclusions that plaintiff suffered an 'ascertainable loss' based on purported price premiums unconnected to specific products); *Franulovic v. Coca-Cola Co.*, No. CV 07-539 (RMB), 2007 U.S. Dist. LEXIS 79732, at *19-20 (D.N.J. Oct. 25, 2007).

Franulovic is instructive on this issue. There, the court found that the plaintiff failed to plead ascertainable loss—a condition precedent for bringing a private NJCFA claim:

> Melfi has not alleged in her Complaint any particulars as to her own experience with Enviga. The only specific allegation is that she purchased Enviga. She has not alleged when she purchased Enviga or for what price, how much of the beverage she purchased and consumed, which advertising

[21] Plaintiffs fail to allege facts to support this conclusory allegation. For example, Plaintiffs do not allege that they applied the Products as directed; expected the Products to protect against the sunburn despite swimming or sweating; and went swimming, but that the Products failed to protect against sunburn.

> enticed her to buy Enviga, her expectations for Enviga based on the advertising, or Enviga's failure to live up to those expectations. Instead, Melfi has alleged general statements that Enviga's claims are false and misleading to the majority of "average reasonable consumers." While it could be implied that Melfi's allegations concerning the "average reasonable consumer" are also her own, such an implication is insufficient, however, because her claim is based on a statute that requires a plaintiff to plead a particularized ascertainable loss in order to have standing to bring such a claim.

Franulovic, 2007 U.S. Dist. LEXIS 79732, at *19-20.

Similarly here, Plaintiffs' Amended Complaint is devoid of any specific factual allegations sufficient to plead "ascertainable loss." Their NJCFA claims, therefore, must be dismissed. *See, e.g., id.*; *see also Glushakow*, 2011 U.S. Dist. LEXIS 90586, at *7-8 (without such "date[s], time[s] and place[s] of the alleged fraud" or other "precision or some measure of substantiation," Plaintiffs' claims do not meet the requirements of Rule 9(b) and should therefore be dismissed).

2. Plaintiffs Fail to State A Plausible Claim For Breach of Express Warranty.

The Court should dismiss Plaintiffs' express warranty claims in their entirety, or in part, for two reasons: (1) any express warranty claims purportedly based on purchases that predate December 6, 2008, are barred under the applicable four-year statute of limitation; and (2) Plaintiffs fail to plead facts sufficient to demonstrate that any alleged warranties were made in connection with the marketing, promotion or advertising of the Products or that such alleged warranties

became part of Plaintiffs' bargain. Moreover, to the extent Plaintiffs allege any direct purchases from Defendants, they fail to plead that they provided the requisite pre-litigation notice of the breach.[22]

Any express warranty claim based on purported purchases during the six-year class period is barred in part by New Jersey's four-year statute of limitations for express warranty claims. N.J.S.A. § 12A:2–725. As such, any claims for breach of warranty for purported purchases predating December 6, 2008 must be dismissed. *See id.*; *Coyle v. Hornell Brewing Co.*, No. 08-02797 (JBS), 2010 WL 2539386, at *6-7 (D.N.J. June 15, 2010).

Additionally, to the extent Plaintiffs' Amended Complaint is asserting express warranty claims based on anything other than the three identified terms on

[22] As Plaintiffs acknowledge, Defendants directly sell the Products through their websites. (FAC ¶ 20.) New Jersey adopted the Uniform Commercial Code's ("UCC") notice requirement to sellers for an express warranty claim. *See Luppino v. Mercedes-Benz USA, LLC*, No. 09-5582, 2011 U.S. Dist. LEXIS 65495, at *7 (D.N.J. June 20, 2011); *JOC, Inc. v. ExxonMobil Oil Corp.*, No. 08-5344 (FSH), 2010 U.S. Dist. LEXIS 32305, at *14 (D.N.J. Apr. 1, 2010). Pre-suit notice of any alleged breach is a condition precedent to bringing an express warranty action against sellers. *See, e.g.*, *Luppino*, 2011 U.S. Dist. LEXIS 65495, at *7; *see also Kury v. Abbott Labs., Inc.*, No. 11-803, 2012 U.S. Dist. LEXIS 4862, at *21 (D.N.J. Jan. 17, 2012) (dismissing express warranty claim against manufacturer where no pre-suit notice given); *JOC*, 2010 U.S. Dist. LEXIS 32305, at *14. Because Plaintiffs fail to plead with any particularity as to where they allegedly purchased the Products, Defendants move to dismiss any express warranty claims based on Products allegedly purchased directly from Defendants through their websites for failing to provide the requisite notice.

the Products' labeling,[23] Plaintiffs fail to allege what warranties were made in connection with those sources, or that such alleged warranties became part of Plaintiffs' bargain in their purchases. To plead an express warranty claim, Plaintiffs must allege that Defendants made an affirmation, promise or description about a product; that that warranty became part of the basis of the bargain for purchasing the product; and that the product failed to perform as described. *See Arlandson v. Hartz Mt. Corp.*, 792 F. Supp. 2d 691, 706 (D.N.J. 2011); *see also* N.J.S.A. § 12A:2-313; *Cipollone v. Liggett Grp., Inc.*, 893 F.2d 541, 567 (3d Cir. 1990) *overruled on other grounds*, 505 U.S. 504 (1992) (plaintiff must establish that "she read, heard, saw or knew of the advertisement containing the affirmation of fact or promise" to satisfy the 'basis of bargain' requirement) .

Plaintiffs allege that they viewed the terms "sunblock," "waterproof," and "sweatproof" on the Products' labeling prior to their alleged purchases and the Products allegedly failed to conform to those warranties. (FAC ¶¶ 12, 75.) Plaintiffs do not, however, allege that they viewed *any other source* containing these, or any other, alleged warranties. As such, to the extent Plaintiffs allege express warranty claims based on Defendants' marketing or advertising materials,

[23] It is unclear what Plaintiffs mean by "other similar uniform representations disseminated by Defendants." (FAC ¶ 72.) This potentially includes other language contained on the labels themselves, as well as marketing and advertising materials. Because of the ambiguity, Defendants move to dismiss any express warranty claims purportedly based on anything other than the terms "sunblock," "waterproof," and "sweatproof" contained on the products' labeling.

or any other alleged warranties, those claims must be dismissed. *See Cipollone*, 893 F.2d at 567; *Fishman v. GE*, No. 2:12-CV-00585 (WJM), 2013 U.S. Dist. LEXIS 61389, at *13-14 (D.N.J. Apr. 30, 2013) ("Plaintiffs do not identify any specific affirmations of fact or promises, and do not provide the language of any advertisements, promotional or marketing materials, point-of-sale displays, or product specifications. Without the language of the warranty, and a start date and end date for the warranty, Plaintiffs cannot state a breach of express warranty claim."); *Hughes v. Panasonic Consumer Elecs. Co.*, No. 10-846 (SDW), 2011 U.S. Dist. LEXIS 79504, at *59 (D.N.J. July 21, 2011) (dismissing express warranty claims where "none of the plaintiffs allege[d] that they were aware of th[e] affirmation of fact at the time of purchase").

3. Plaintiffs Fail to State A Claim Under the New Jersey Truth-in Consumer Contract, Warranty and Notice Act.

Plaintiffs also fail to state a claim under the TCCWNA, which requires that: (1) the plaintiff is a consumer within the statute's definition; (2) the defendant is a seller; (3) the defendant (a) offers or enters into a written consumer contract, or (b) gives or displays any written consumer warranty, notice, or sign; and (4) the offer or written contract, warranty, notice or sign included a provision that violates any clearly established legal right of a consumer or responsibility of a seller. *See Watkins v. DineEquity, Inc.*, No. 11-7182 (JBS/AMD), 2012 U.S. Dist. LEXIS 122677, *6-7 (D.N.J. Aug. 28, 2012). Here, Plaintiffs cannot establish that any

"clearly established legal right" was violated.

As discussed *supra*, any claim based solely on an alleged violation of the FDCA or its implementing regulations is preempted. Plaintiffs are thus left with only their alleged NJCFA and express warranty claims as possible grounds to establish a violation of a "clearly established legal right." (FAC ¶ 81.) But, as demonstrated above, Plaintiffs cannot plead a plausible NJCFA or breach of express warranty claim. As such, to the extent the terms "sunblock," "waterproof," and "sweatproof," are warranties, Plaintiffs cannot show that those warranties violated a "clearly established right." The Court should dismiss Plaintiffs' TCCWNA claims on this basis.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss should be granted and Plaintiffs' Amended Complaint should be dismissed in its entirety without leave to amend.

Dated: May 24, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 24, 2013, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on counsel for Plaintiff via transmission of Notices of Electronic Filing generated by CM/ECF.